factsheet

Radiation Sterilisation of Advanced Drug-Device Combination Products

Advanced Drug-Device combination products can offer significant advantages over conventional but independently used drugs and devices. The advantages include efficiency, performance and convenience but combining materials and biologics can create challenges especially in sterilising the Drug-Device product.

iia

The Challenge

The International Irradiation Association (iia) has long recognized that healthcare companies that manufacture sophisticated and high value products face challenges in achieving a Sterility Assurance Level (SAL) of 10`6 without adverse impact on performance and/or the functionality of the advanced drug-devices combination products.

It is understood that regulators, when comparing sterilization methodologies, prefer terminal sterilisation to aseptic processing as the ability to validate the logarithmic reduction in microbial contamination reduces the risk of a contaminated product causing infection or transmitting a disease to the patient.

The challenges associated with sterilisation and SAL were highlighted when the iia organised a workshop in San Diego, California, U.S.A. December 2006. The workshop was well attended and resulted in a paper being published in Medical Device Technology in March 2007. The paper is still available to iia members via our website.[1] Over the next few years several further workshops were organised and the topic was addressed at the International Meeting on Radiation Processing (IMRP) in London 2008, Montreal 2011, Shanghai 2013 and Vancouver 2016.

The workshops and conferences reflected on possible changes to dose setting for drug-device combination products and concluded that iia should engage with representatives from the regulatory authorities including the Office of Combination Products (formed by the Food and Drug Administration in December 2002 to regulate products comprised of two or more regulated components) and with the US Department of Health and Human Services, Food and Drug Administration, Code of Federal Regulations 21 (CFR) Part 3.2.[1]

Recent Developments

Since 2006 the medical device community and regulators have debated these issues at various international healthcare meetings. The planned introduction of ISO Standard TS 19930 "Guidance on aspects of a risk-based approach to assuring sterility of terminally sterilized, single-use health care product that is unable to withstand processing to achieve maximally a sterility assurance level of 10-6"[3] represents significant progress and means that manufacturers will shortly be able to consider an alternative SAL as well as aseptic sterilization for products.

---

1 Radiation Sterilisation of Advanced Drug Device Combination Products.
2 FDA/Combination Products.
3 ISO Standard TS19930

iia Communicate. Educate. Advocate.
info@iiaglobal.com
iiaglobal.com